

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20251  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,935	05/03/2001	David F. Woodward	D2914	6555
7590	07/15/2002			
Frank J. Uxa Stout, Uxa, Buyan & Mullins, LLP Suite 300 4 Venture Irvine, CA 92618			EXAMINER FUBARA, BLESSING M	
		ART UNIT 1615	PAPER NUMBER 7	
DATE MAILED: 07/15/2002				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/847,935	WOODWARD ET AL.
Examiner	Art Unit	
Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on paper no. 6.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 36-68 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 36-68 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

Examiner acknowledges receipt of IDS, request for extension of time and amendment A filed 04/29/02. New claims 36-68 are pending.

### ***Claim Rejections - 35 USC § 112***

1. New claims 36-68 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
2. Applicant's arguments filed 04/29/02 have been fully considered but they are not persuasive.

Applicants specifically argue that claims 13, 14 and 20 have been amended and the corresponding claims in the new version are 48, 49 and 53. The new claims are confusing because the claims do not further limit the composition of claim 36.

Applicants also argue that the term derivatives in the claims refers to cyclodextrin derivatives. It may be pointed out that as mentioned or stated by applicants in the response filed 04/29/02, cyclodextrins are defined in the specification as anionic polysaccharides (page 17, paragraph 2) and cyclodextrin derivatives are given on page 18 of the specification. However, it is not clear what derivatives the claims are referring to. Applicants are invited to read the claims as written and examiner submits that applicants would find that the introduction of derivatives in the middle of the claims, after fatty acids (claim 36) and after quinoxaline (claim 40) for example is confusing. In these two exemplary claims, derivatives refer to fatty acid derivatives and quinoxaline derivatives. There is now therefore, more than one interpretation for derivatives. The claims are confusing and thus indefinite.

Since cyclodextrin derivatives are described in the specification, applicants may overcome this rejection by specifically amending the claims to recite the invention, that is, cyclodextrin derivatives without the introduction of new matter.

New claims 36 and 60 are confusing (see lines 6-8 of claim 36 and 7-10 of claim 60).

***Claim Rejections - 35 USC § 102***

3. New claims 36-39, 41-44, 46-48 and 59-62 remain rejected under 35 U.S.C. 102(b) as being anticipated by Hanssler et al. (Derwent Database on West, DE 3309765).
4. New claims 36, 37, 41-44, 46-48, 60 and 64 remain rejected under 35 U.S.C. 102(b) as being anticipated by FR 2272684 (Derwent Database on west).
5. New claims 36, 37, 41-44, 46-48, 60 and 64 remain rejected under 35 U.S.C. 102(b) as being anticipated by JP 62048618 (Derwent Database on West).
6. Applicant's arguments filed 04/29/02 have been fully considered but they are not persuasive.

Applicants argue that each of the rejection is inappropriate because, none of the cited references, Hanssler, FR 2272684 or JP 62048618 teaches a complex of therapeutic agent with efficacy enhancing component.

It may be noted that efficacy-enhancing components are selected from the group consisting of "fatty acids, derivatives and mixtures thereof." The claims broadly recite a composition comprising a therapeutic agent and an efficacy enhancing component and the therapeutic agent is in complex with the efficacy-enhancing component. The prior art teaches the composition and it is inherent that a complex forms in a mixture of therapeutic component and efficacy enhancing component. There is nothing in the claims that indicates that such a

mixture would not form in the prior art. Hanssler teaches a composition that comprises quinoxaline.

***Double Patenting***

7. New claims 36-68 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 09/848,249. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims a composition comprising a therapeutic agent and efficacy enhancing components in the generic claim. The therapeutic agent claimed is alpha-2-adrenergic agonist (claim 4) and the efficacy-enhancing component is selected from the group consisting of anionic polymers and fatty acids (generic claim 1). The copending application number 09/848249 claims a composition comprising alpha-2-adrenergic agonist and fatty acids in the generic claim.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Although, the copending application has not been issued as a patent, the rejection is maintained and the provisional rejection is proper.

7. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara  
July 11, 2002

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600